

Notice of Allowability	Application No.	Applicant(s)	
	10/776,245	ANTONSSON ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/13/07.
2. ☒ The allowed claim(s) is/are 1, 3-38, 47-49 and 52-65.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/776,231.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>5/14/2007</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1, 3-38, 47-49 and 52-65 are pending.

Applicants' amendment filed August 13, 2007 is acknowledged. Applicants' response has been fully considered. Claim 1 has been amended. Since the product claims are allowable, the method claims (i.e., claims 47-49 and 59-65) are included for examination. Therefore, claims 1, 3-38, 47-49 and 52-65 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claims 1, 3-5, 8, 13-23, 26-30, 33-38, 53 and 56-58 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendment to the claims, and applicants' response at pages 16-17 in the amendment filed August 13, 2007.

Withdrawn Claim Rejections-Obviousness Type Double Patenting

3. The previous rejection of claims 1, 3-38 and 52-58 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 and 45 of U. S. Patent 6,262,028, is withdrawn in view of applicant's submission of a terminal disclaimer, and applicants' response at page 17 in the amendment filed August 13, 2007.
4. The previous rejection of claims 1, 10-13, 31-35, 37 and 52-58 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 and 45 of U. S. Patent 5,965,692, is withdrawn in view of applicant's submission of a terminal disclaimer, and applicants' response at page 17 in the amendment filed August 13, 2007.

Examiner's Amendment

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Leonard Mitchard on October 25, 2007.

Examiner's Amendment to the Specification:

Please replace the paragraph which has been inserted to the page 1 of the specification and indicated in the page 2 of the preliminary amendment filed February 12, 2004 with the following paragraph:

This application is a continuation of U. S. Application No. 10/074,008, filed February 14, 2002, now abandoned, which is a continuation of U. S. Application No. 09/708,449, filed November 9, 2000, now abandoned, which is a continuation of U. S. Application No. 09/353,644, filed July 15, 1999, now U.S. Patent 6,262,028, which is a continuation of U. S. Application No. 08/776,231, filed January 31, 1997, now U.S. Patent No. 5,965,692, which is a 371 of PCT/SE96/01680, filed December 17, 1996, the entire content of which is hereby incorporated by reference in this application.

Examiner's Amendment to the Claims:

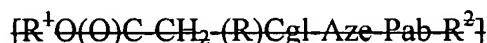
Claims 6, 47, 53-56 and 59-65 have been amended as follows:

6. (Currently amended) A formulation, as defined in Claim 1, wherein, in the compound of formula I, A¹ represents C₁₋₃ alkylene, and R⁴ represents H or C₁₋₃ alkyl and R⁵ represents C₂₋₆ alkyl or C₅₋₆ cycloalkyl, or R⁴ and R⁵ together represent pyrrolidinyl when R¹ represents -A¹C(O)N(R⁴)R⁵.

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47. (Currently amended) A method of treatment of a condition where inhibition of thrombin is required which method comprises administration of a therapeutically effective amount of a formulation as defined in Claim 1 or claim 52, ~~or a pharmaceutically acceptable salt thereof~~, to a person suffering from, or susceptible to, such a condition for a time and under conditions suitable for eliciting an antithrombotic effect.

53. (Currently amended) A combination product comprising (a) acetylsalicylic acid and (b) a compound of the formula I as defined in claim 1;



54. (Currently amended) A combination product comprising (a) ~~acetylsalicylic~~ acetylsalicylic acid and (b) the compound $\text{EtOOCCH}_2-(\text{R})\text{Cgl-Aze-Pab-OH}$ or a pharmaceutically-acceptable salt thereof.

55. (Currently amended) A combination product comprising (a) ~~acetylsalicylic~~ acetylsalicylic acid and (b) the compound $\text{EtOOCCH}_2-(\text{R})\text{Cgl-Aze-Pab-OH}$.

56. (Currently amended) A combination product as claimed in Claim 53 which comprises a kit of parts comprising components (a) and (b).

59. (Currently amended) A method of treatment of a condition where inhibition of thrombin is required, which method comprises administration of an effective amount of a combination product as claimed in Claim 53 for a time and under conditions suitable for eliciting an antithrombotic effect.

60. (Currently amended) A method of treatment of a condition where inhibition of thrombin is required, which method comprises administration of an effective amount of a combination product as claimed in Claim 54 for a time and under conditions suitable for eliciting an antithrombotic effect.

61. (Currently amended) A method of treatment of a condition where inhibition of thrombin is required, which method comprises administration of an effective amount of a

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combination product as claimed in Claim 55 for a time and under conditions suitable for eliciting an antithrombotic effect.

62. (Currently amended) A method of treatment of a condition where inhibition of thrombin is required, which method comprises administration of a therapeutically effective amount of components (a) and (b) of a combination product as claimed in Claim 53 separately, sequentially or simultaneously for a time and under conditions suitable for eliciting an antithrombotic effect.

63. (Currently amended) A method of treatment of thrombosis or of hypercoagulability in blood and tissues, which comprises administration of an effective amount of a combination product as claimed in Claim 53 for a time and under conditions suitable for eliciting an antithrombotic effect.

64. (Currently amended) A method of treatment of thrombosis or of hypercoagulability in blood and tissues, which comprises administration of an effective amount of a combination product as claimed in Claim 54 for a time and under conditions suitable for eliciting an antithrombotic effect.

65. (Currently amended) A method of treatment of thrombosis or of hypercoagulability in blood and tissues, which comprises administration of an effective amount of a combination product as claimed in Claim 55 for a time and under conditions suitable for eliciting an antithrombotic effect.

The following is an **Examiner's Statement of Reasons for Allowance**: The following references appear related to the claimed invention. Antonsson *et al.* (U.S. Patent 6,262,028 B1) claim a compound of formula I, $R^1O(O)C-CH_2-(R)Cgl-Aze-Pab-R^2$, where R^1 and R^2 each is defined in the specification; a pharmaceutical formulation including a compound of formula I or a pharmaceutically acceptable salt thereof, in admixture with a pharmaceutical carrier; and a pharmaceutical formulation comprising an effective amount of acetylsalicylic acid and a compound of formula I, $R^1O(O)C-CH_2-(R)Cgl-Aze-Pab-R^2$; and Gustafsson *et al.* (U. S. Patent 5,965,692) claim a compound of formula I, $R^1O(O)C-CH_2-(R)Cgl-Aze-Pab-R^2$, where R^1 is H or C_{1-10} alkyl, and R^2 is OH, and a pharmaceutical formulation including a compound of formula I or a pharmaceutically acceptable salt thereof, in admixture with a pharmaceutical carrier, and the

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specification discloses the compounds of invention may be combined and/or co-administered with an antiplatelet agent such as acetylsalicylic acid, and an effective doses of the compound of formulation I can be used in the treatment. While the scope of the claims of these two patents are overlapped with the scope of the claims of the instant application, a terminal disclaimer has been filed over these two patents. Therefore, the claims are allowable over the art of record.

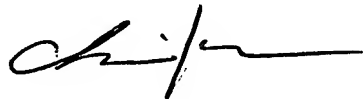
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK
October 25, 2007